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K964959

**510(k) SUMMARY**  
**VASCUTEK TWILLWEAVE™ VASCULAR GRAFT**

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The Twillweave™ vascular graft is a woven polyester graft, with a porosity of 350 ml/min/cm<sup>2</sup> which is available in a straight tube and bifurcated configurations. The Twillweave™ Vascular Graft is indicated for repair or replacement of damaged and diseased vessels of the arterial system in cases of aneurysmal or occlusive disease.

The Twillweave™ vascular graft is manufactured from materials that have an extensive history of use in cardiovascular and other medical applications. This polyester material has been thoroughly tested and characterized with regard to biocompatibility and suitability for its intended use. The Twillweave™ vascular graft is supplied sterile and must be preclotted prior to use. The method of sterilization used is Ethylene Oxide. A shelf-life of 5 years has been established for the Vascutek Twillweave™ vascular graft.

CarboMedics considers the Vascutek Twillweave™ vascular graft to be substantially equivalent to the Vascutek Gelweave™ vascular graft in intended use, base material (polyester), and function. Side-by-side in-vitro performance testing has been performed on the Vascutek Twillweave™ straight and bifurcated vascular grafts and the predicate device. In-vitro performance testing performed on the Twillweave™ including burst strength, suture retention, tensile strength and base graft (water) porosity provides evidence that the Twillweave™ vascular graft is substantially equivalent to the Vascutek Gelweave™ vascular graft. Animal testing has demonstrated acceptable in-vivo performance for the Twillweave™ graft's intended purpose.

CarboMedics considers the Vascutek Twillweave™ vascular graft safe, effective, and substantially equivalent in intended use, base material (polyester), and function to the Vascutek Gelweave™ vascular graft which received marketing clearance on December 19, 1995 510(k) via K952293.

Common name of the device:	Prosthesis, Vascular Graft
Trade or Proprietary name:	Vascutek Twillweave™ vascular graft
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